IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ZOLOFT (SERTRALINE HYDROCHLORIDE) PRODUCTS LIABILITY LITIGATION	:	**MDL No. 2342**
	:	**2:12-md-02342-CMR**
THIS DOCUMENT RELATES TO:	:	**HON. CYNTHIA M. RUFE**
Vicki Grube and Shane Grube, Individually and as Parents and Natural Guardians of Plaintiff K.S.G., a Minor **Case No. 2:12-cv-05122- CMR**	:	
Candice Rodriguez, Individually and as Parent and Natural Guardian of Plaintiff R.R., a Minor **Case No. 2:15-cv-00389-CMR**	:	
Emily A. Wearda, Individually and as Parent and Natural Guardian of Plaintiff J.R.W., a Minor **Case No. 2:15-cv-00390-CMR**	:	

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION TO DISMISS PURSUANT TO F.R.C.P. 41(a)(2)

Plaintiffs Vicki Grube and Shane Grube, Individually and as Parents and Natural Guardians of Plaintiff K.S.G., a Minor; Candice Rodriguez, Individually and as Parent and Natural Guardian of Plaintiff R.R., a Minor; and Emily A. Wearda, Individually and as Parent and Natural Guardian of Plaintiff J.R.W., a Minor, ("Plaintiffs") respectfully submit this memorandum in support of their motion to dismiss the above entitled actions without prejudice.

I. MINOR PLAINTIFFS SHOULD BE ALLOWED TO DISMISS THEIR CLAIMS *WITHOUT PREJUDICE*

A. The Court Should Allow The Individual Minor Plaintiffs To Dismiss Their Claims *Without Prejudice* Under Rule 41(a)(2)

Dismissals under Rule 41 should be generally granted *without prejudice* "unless defendant will suffer some prejudice other than the mere prospect of a second suit." *In re Paoli R.R. PCB Litig.*, 916 F.2d 829, 863 (3d Cir. 1990) ("*In re Paoli I*") (quoting 5 J. Moore, *Moore's Federal Practice* para. 41.05[1], at 41-62 (1988)); *In re Wellbutrin XL Antitrust Litig.*, 268 F.R.D. 539, 543 (E.D. Pa. 2010) ("Dismissal, however, should be generally granted unless it would subject 'the defendant to plain prejudice beyond the prospect of subsequent litigation.'"). Indeed, as judges in this district and elsewhere have consistently recognized, "[p]rejudice is not shown by the mere prospect of a second lawsuit, or that the plaintiff will obtain some tactical advantage in future litigation." *Total Containment, Inc. v. Aveda Mfg. Corp.*, 1990 U.S. Dist. LEXIS 16637, at 7 (E.D. Pa. Dec. 7, 1990) (citing *Peifer v. Royal Bank of Canada*, 121 F.R.D. 39, 41 (M.D. Pa. 1986) (quoting 9 C. Wright & A. Miller, Federal Practice & Procedure § 2363 at 165 (1971))). See also *Puerto Rico Maritime Shipping Authority v. Leith*, 668 F.2d 46, 50 (1st Cir. 1981) ("Neither the prospect of a second suit nor a technical advantage to the plaintiff should bar the dismissal" without prejudice under Rule 41(a)(2)). This is because ". . . the prospect of subsequent suit is inherent to every action dismissed without prejudice; on its own, it cannot logically form the basis of an argument that Defendant is harmed by the dismissal

sufficient to deny it." *Loose v. N. Wildwood City*, 2012 U.S. Dist. LEXIS 18005, at 3 (D.N.J. Feb. 14, 2012). In other words, "[t]he prejudice to the defendant must be 'substantial.'" *Total Containment*, 1990 U.S. Dist. LEXIS 16637, at 7. For example, the mere "allegation that plaintiff should not be permitted to abuse the judicial process is insufficient to warrant dismissal with prejudice." *Peifer*, 121 F.R.D. at 41.

Voluntary dismissal under Rule 41(a)(2) falls within the "broad discretion" of the district court. *Barron v. Caterpillar, Inc*., 1996 U.S. Dist. LEXIS 11496, at 4 (E.D. Pa. Aug. 5, 1996). In determining whether the defendant will suffer plain prejudice beyond the prospect of a second suit or that plaintiff will gain some tactical advantage, courts consider: "(1) [t]he excessive and duplicative expense of a second litigation; (2) [t]he effort and expense incurred by the defendant in preparing for trial; (3) [t]he extent to which the current suit has progressed; and (4) [the] Plaintiff's diligence in bringing the motion to dismiss." *Maleski v. DP Realty Trust*, 162 F.R.D. 496, 498 (E.D. Pa. 1995). "Plaintiff's reasons for seeking withdrawal are irrelevant to prejudice." *Loose*, 2012 U.S. Dist. LEXIS 18005, at 3, n.1.

A balancing of these factors strongly supports allowing any individual minor Plaintiff in this MDL to dismiss his or her case *without prejudice*. Fact discovery is not complete and no case-specific expert discovery has been conducted in any of the MDL cases. With respect to those non-cardiac birth defect cases which are not part of the discovery pool of potential bellwether cases, over 225 individual cases have not progressed much past the pleadings phase because only PFS responses have been submitted. Moreover, while it is appropriate to consider the cost and expense to the defendant when considering the prospect of future litigation, consideration must also be given to the rights of the plaintiff, especially when the plaintiff is a child.

1. Dismissal Is Generally Allowed *Without Prejudice* Where Claims May Be Supported By Future Events Or Later Epidemiological Evidence

That a "plaintiff may be able to conduct further investigation and fill crucial gaps in the evidence" has "been held not to constitute sufficient prejudice" to prevent dismissal without prejudice. Hon. William W. Schwarzer et al., Federal Civil Procedure Before Trial. (Nat'l ed.

(Westlaw 2015), ¶ 16:346, 16:351 (citing *Cone v. W. Va. Pulp & Paper Co.*, 330 U.S. 212, 217 (1947)). Rather, such considerations support allowing dismissal without prejudice. It is well-established that where there are events that may occur in the future that could affect a plaintiff's case, it is appropriate to dismiss an action without prejudice rather than granting summary judgment so that the plaintiff may pursue his or her claim when and if future events make the claim viable. *See, e.g., In re Paoli I*, 916 F.2d at 863.

The rationale underlying this rule and allowing dismissal *without prejudice* is even stronger when actions involve the rights of minor plaintiffs whose claims may be supported by later or developing epidemiological evidence. *See In re Agent Orange Prods. Liab. Litig.*, 603 F.Supp. 239, 245-46 (E.D.N.Y. 1985), *aff'd in part and rev'd in part on other grounds*, 818 F.2d 194 (2d Cir. 1987) ("*In re Agent Orange*").

a. *In re Paoli I* Supports Allowing Dismissals *Without Prejudice*

In re Paoli I supports allowing the individual plaintiffs who have cases in this litigation to dismiss their claims without prejudice. That case involved an action by certain plaintiffs alleging they were harmed by PCBs, but later admitted that they did "not currently suffer from any adverse health effects as a result of their exposure to PCBs." *In re Paoli I*, 916 F.2d at 863. The defendants moved for summary judgment. In response, the plaintiffs sought to dismiss their personal injury claims without prejudice. The defendants opposed dismissal without prejudice, arguing they would be unfairly prejudiced by the possibility of having to defend such claims in the future after already investing substantial time and resources litigating them. The district court denied the plaintiffs' Rule 41 motion and granted the defendants' motion for summary judgment. *See id.* at 837.

Noting the "liberal policy" under Rule 41 and finding that the defendants would not be "significantly prejudiced," the Third Circuit Court of Appeals held that the district court abused its discretion by granting summary judgment rather than allowing the plaintiffs to dismiss their personal injury claims without prejudice under Fed. R. Civ. P. 41(a)(2). *Id.* at 863.

b. *In re Agent Orange Prods. Liab. Litig*. Is On Point

In re Agent Orange also supports allowing the minor Plaintiffs in this MDL to dismiss their claims *without prejudice*. *See In re Agent Orange Prods. Liab. Litig*., 603 F.Supp. at 247-48. In that case, the plaintiffs were children who filed personal injury claims against the government, claiming that they were born with birth defects as a result of their father's exposure to Agent Orange while serving in the military in Vietnam. *See id*. at 245-46. The government moved for summary judgment on the ground that there was "as yet no epidemiological evidence that paternal veteran exposure to Agent Orange causes birth defects or miscarriages." *Id.* at 246. While the district court agreed that scientific proof of causation did not exist, it declined to grant summary judgment. Instead, because of the prospect that scientific evidence might develop in the future, the district court allowed the minor plaintiff's claims to be dismissed *without prejudice*. *See id*. at 247-48. As then-Chief Judge Jack Weinstein explained:

> The court agrees that ***it would be both reasonable and fair to avoid dismissing the children's claims on the merits when the scientific evidence may not as yet have been fully developed***. The [defendant] . . . strongly urges that the infants' cases be dismissed on the merits and with prejudice so that they can never sue again, even if evidence subsequently shows that they have a valid claim against the [defendant].
>
> Rule 41(a)(2) of the Federal Rules of Civil Procedure grants the court broad discretion to permit a voluntary withdrawal without prejudice at this stage of the litigation. Absent a showing of substantial harm to the defendant, ***discretion should generally be exercised in favor of an infant who lacks evidence to support his or her claim but who may obtain such evidence in the future.*** Added reason to favor the infants exists when, as here, following the [defendants'] view would bar a handful of children who have already sued while leaving thousands of potential claimants who have not sued free to do so in the future. . . .
>
> The prospect of defending a future lawsuit by these plaintiffs does not constitute 'plain legal prejudice' to the [defendant]. ***It would be unfair to dismiss on the merits the claims of infant children*** whose counsel did not move for voluntary dismissal. ***All infants' claims are, therefore, dismissed without prejudice.***

Id. at 247-48 (emphasis added) (internal citations omitted).

Like the plaintiffs in *In re Paoli I* and *In re Agent Orange*, some of the minor Plaintiffs' injuries in this litigation may lack the epidemiological evidence to fully support their claims. It

often takes a substantial period of time for epidemiological data to accumulate for very rare birth defects. Similar to *In re Paoli I* and *In re Agent Orange*, the minor Plaintiffs here should not be barred from asserting claims that may be viable and pursued by others in the future. There is no "significant prejudice" to Pfizer under the circumstances. As *In re Agent Orange* makes clear, it would be unfair to dismiss the claims of the minor plaintiffs with prejudice simply because the minor plaintiffs have pursued legal rights while other children who have not yet exercised their legal rights remain free to bring similar injury claims in the future. *See In re Agent Orange* 603 F.Supp.2d at 247-48.[1]

The minor Plaintiffs in this litigation – through no fault of their own – were born with birth defects that they will live with for the rest of their lives. They did not choose to expose themselves to Zoloft. They did not decide to file their lawsuit against Pfizer. It would be unfair and unreasonable to punish the minor Plaintiffs by dismissing their claims with prejudice and forever foreclosing them from pursuing their claims simply because the epidemiological data might not presently exist for their rare birth defect(s) under *Daubert* and/or because of the timing of their parents' decision to file a lawsuit on their behalf now as opposed to a later time or in a different court.

[1] *In re Agent Orange* is the seminal decision on this issue. *See*, *e.g.*, Am. Law. Prod. Liab. 3d § 50:46, Voluntary Dismissals (Westlaw 2015) ("Discretion should generally be exercised in favor of a minor plaintiff who lacks evidence to support a claim, but who may obtain such evidence in the future. This is especially true when a large number of children may have been injured, and a dismissal with prejudice would bar a handful of these children who have already sued, while leaving thousands of potential claimants who have not sued, free to do so in the future."); 63B Am. Jur. 2d Prods. Liab. § 1564 (Westlaw 2015) (same); Wright & Miller, 9 Federal Practice & Procedure § 2364 (3d ed. (Westlaw 2015) (citing *In re Agent Orange* and observing that dismissal without prejudice is typically permitted "in order to give the plaintiff an opportunity to secure new evidence after the plaintiff has found, by discovery or otherwise, that the claim advanced in the action cannot be proven on the basis of the information then available.").

2. The Cases Previously Cited By Pfizer In Other Briefs Are Distinguishable And Do Not Involve Plaintiffs Who Are Young Children

Pfizer is likely to downplay that this case involves a minor child, but it is a critical distinction between this case and the cases that Pfizer asks this Court to rely upon. "In deciding a [Rule] 41(a)(2) motion, the Court should weigh the equities, and do justice to all the parties in the case." *Mateo v. Empire Gas Co., Inc*., 287 F.R.D. 124, 128 (D.P.R.2012) (allowing minor plaintiffs to voluntarily dismiss their personal injury claims without prejudice). Despite Pfizer's ignoring the fact, "[t]he Court cannot overlook that dismissing this case with prejudice against this defendant would deprive minor children . . . of the possibility of refiling this action against [defendant], a potential tortfeasor." *Id*. (citing *In re Agent Orange*, 603 F.Supp. at 248). None of the cases relied on by Pfizer in support of its argument that any dismissals should be with prejudice involve plaintiffs who are children or other factual and legal issues even remotely analogous to this case. This is a distinction *with* a difference.

For example, Pfizer relies most heavily on an unpublished order in *In re Denture Cream Products Liability Litigation* ("*In re Denture Cream*") which Pfizer attached as Exhibit B to its opposition to Plaintiffs' motion to modify Pretrial Order No. 83 [Doc. No. 1169]. Notably, Pfizer fails to point out several key facts which render the case totally distinguishable. For example, Pfizer conveniently chose to avoid including key language that was central to the *In re Denture Cream* order. Pfizer's opposition brief claims: "As another MDL court recently observed, an order **'**granting Defendants' motion to exclude all or part of the testimony of Plaintiffs' general causation expert witnesses [is] case-dispositive.'" *Id*. at p. 8 [Doc. No. 1169]. But that is <u>*not*</u> what the Court actually said. Below is an excerpt of what the order actually says (with the omitted part highlighted):

Pfizer chopped the actual sentence with quoted language in half without indicating as much in its brief to this Court. Pfizer excluded the other half of the sentence (the highlighted part) wherein the court recited that the plaintiff had <u>stipulated that the order was dispositive</u>. (*In re Denture Cream* order, Ex. B) (Doc. 1169-2, at ¶ 1).

ORDERED AND ADJUDGED that:

1. The Court agrees with Plaintiffs' stipulation that the January 28, 2015 Order granting Defendants' motion to exclude all or part of the testimony of Plaintiffs' general causation expert witnesses [ECF No. 2294] (the "January Order") was case-dispositive. All of

Pfizer also neglected to note that the *In re Denture Cream* court dismissed the case with prejudice in response to the *Defendants' motion* to dismiss, which *the plaintiff did not oppose*, and did so in large part "[i]n light of the parties' stipulation that the [order was] dispositive[.]"(*In re Denture Cream* order, Ex. B) (Doc. 1169-2, at ¶¶ 1, 2), as shown below:

2. In light of the parties' stipulation that the January Order is case-dispositive, Defendants have moved pursuant to Rule 56 for entry of final judgment as to, and the dismissal with prejudice of, all causes of action against Defendants. Plaintiffs do not oppose this motion, because they acknowledge that the January Order is case-dispositive, but reserve their rights at law to appeal the Court's January Order to the United States Court of Appeals for the Eleventh Circuit. Accordingly, Defendants' motion is **GRANTED**, and all of Plaintiffs' causes of action against Defendants are **DISMISSED** in their entirety **WITH PREJUDICE**, subject only to Plaintiffs' rights at law to appeal to the United States Court of Appeals for the Eleventh Circuit this Court's January Order as well as the instant Order.

Those facts are clearly not applicable here. Unlike *In re Denture Cream*, the Plaintiffs have not stipulated that the *Daubert* rulings are dispositive. To the contrary, they are not. Furthermore, in contrast to *In re Denture Cream*, the Plaintiffs oppose any dismissal with prejudice. Finally, unlike this case, unlike *Mateo*, and unlike *In re Agent Orange*, the order involving the plaintiff in *In re Denture Cream* did not involve children, nor do any of the cases cited or relied on by Pfizer. Finally, Pfizer does not even mention – let alone attempt to distinguish – the seminal case on this subject (*In re Agent Orange*), despite the fact that that case supports allowing the minor Plaintiffs in this litigation to dismiss their claims without prejudice. Under *In re Agent Orange*, *In re Paoli I*, and in accordance with the "broad" and "liberal"

discretion this Court has under Rule 41(a)(2), the Court should allow the minor Plaintiffs to dismiss without prejudice.

II. The Scientific Data Regarding SSRIs, Including Zoloft, And Birth Defects Is Not Static: New Developments Continue To Emerge

New studies have come out *after* the *Daubert* hearing in this MDL and epidemiological data are constantly being published. By comparison to cardiac birth defects, many of the non-cardiac birth defects that are alleged to have been caused by prenatal exposure to SSRIs, including Zoloft, are extremely rare. For example, the background rate of spina bifida (which is a neural tube defect) is only 3 out of every 10,000 births. *See* http://www.cdc.gov/ncbddd/spinabifida/data.html. Consequently, it is extremely difficult and it takes time for epidemiological data regarding such defects to accumulate and be analyzed. But important new epidemiological studies are beginning to emerge, with many having been published *after* the *Daubert* hearing in early 2014.

For example, in a publication by Knudsen, et al. (2014)[2] the authors concluded that "based on data with high case ascertainment . . . maternal use of SSRIs during the first trimester increases the risk of severe CHD [congenital heart defects]." *Id*. at p. 1. Specifically, "Table 2 shows that maternal exposure to any SSRI during first trimester was associated with an increased risk of severe CHD of a factor four." *Id*. at p. 4. In a study published by Furu, et al. (2015), [3] the authors reported statistically significant increased risks for cardiac birth defects and septal defects for SSRIs as a class. In addition, the authors reported that sertraline in particular was "associated with an increased prevalence of clubfoot . . . and anal atresia," both of which represented statistically significant findings. *Id*. at p. 4. Yazdy, et al. (2014)[4] similarly concluded that their "data suggest an increased risk of clubfoot occurrence in relation to SSRI use." *Id*. at p.

[2] Knudsen, TM. et al. Increased risk of severe congenital heart defects in offspring exposed to selective serotonin-reuptake inhibitors in early pregnancy – an epidemiological study using validated EUROCAT data. *BMC Pregnancy and Childbirth* 2014, 14:333.
[3] Furu, K. et al. Selective serotonin reuptake inhibitors and venlafaxine in early pregnancy and risk of birth defects: population based cohort study and sibling design. *BMJ* 2015;350:h1798.
[4] Yazdy, MM, et al. Use of selective serotonin-reuptake inhibitors during pregnancy and the risk of clubfoot. *Epidemiology*. 2014;25:859–865.

1. And a study and publication by Cray, et al. (2014)[5] reported "results [that] provide confirmatory evidence that citalopram [i.e. the SSRI Celexa] exposure is associated with cellular and morphological alterations of the craniofacial complex, which may have important implications for use during pregnancy." *Id*. When interviewed about his findings, Dr. Cray stated: "There is now convincing evidence that at least some SSRIs are capable of disrupting the normal function and maintenance of the craniofacial development in the fetus, resulting in an elevated risk for specific birth defects." http://academicdepartments.musc.edu/catalyst/archives/2014/11-7Citalopram.html.

These and other recent studies demonstrate that the scientific evidence and epidemiological data regarding prenatal exposure to SSRIs, including Zoloft, and birth defects is not in a permanent state. It is constantly developing and is currently being analyzed with significant interest in the public health community. Ten years ago, despite Pfizer's internal understanding of the risks, there was very little published epidemiological data regarding the risk of SSRIs and septal and cardiac birth defects. There is now substantial evidence that SSRIs, including Zoloft, cause such birth defects. Pfizer's own internal documents acknowledge this fact. In the future, there is likely to be substantial epidemiological data regarding the risk of several other birth defects (cardiac and non-cardiac) associated with SSRIs, including Zoloft. Moreover, the data and analysis by the public health community is likely to be greatly informed by their understanding of what Pfizer and the other drug companies have known for years, continue to privately discuss, and have internally admitted but publicly denied.

[5] Cray, JJ. Jr. et al. Selective Serotonin Reuptake Inhibitor Exposure Alters Osteoblast Gene Expression and Craniofacial Development in Mice. *Birth Defects Res A Clin Mol Teratol*. 2014 Dec;100(12):912-23.

III. CONCLUSION

Based on the foregoing, Plaintiffs respectfully request that their motion be granted and that the minor Plaintiffs be allowed to dismiss *without prejudice*; each side to bear its own costs.

Respectfully submitted,

Dated: May 14, 2015

/s/ Mark P. Robinson, Jr.

Mark P. Robinson, Jr.
ROBINSON CALCAGNIE ROBINSON SHAPIRO DAVIS, INC.
19 Corporate Plaza Drive
Newport Beach, CA 92660
Tel.: 949-720-1288; Fax: 949-720-1292
Beachlawyer51@hotmail.com

Attorney for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on May 14, 2015, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which shall send electronic notification of such filing to all CM/ECF participants.

Dated: May 14, 2015

/s/ *Mark P. Robinson, Jr.*
MARK P. ROBINSON, JR.